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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,374	06/08/2001	Jeffrey C. Rapp	AVI-007N	2448
26739	7590	03/18/2008		
AVIGENICS, INC. 111 RIVERBEND ROAD ATHENS, GA 30605			EXAMINER TON, THAIAN N	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 03/18/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/877,374	<b>Applicant(s)</b> RAPP, JEFFREY C.	
	<b>Examiner</b> Thaian N. Ton	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007 and 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-29,62-70 and 72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-29,62-70 and 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered. Applicants filed remarks on 2/19/08. The Examiner responds to these remarks in this Office action.

Applicants filed no claim amendments with their remarks. Claims 1-5, 9-29, 62-70, and 72 are pending and under current examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-17, 19-29, 62 and 63 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. This rejection is maintained for reasons of record.

*Applicants' Arguments.* Applicants argue that it has been determined that proteins produced in avian oviduct cells (i.e., tubular gland cells) are not fucosylated. Applicants provide Zhu (2005) and Raju et al (2000) and state that this lack of fucosylation in the oviduct cells of chickens is in contrast to what is seen in other cells of the chicken. Applicants argue that this absence of fucose alters the therapeutic utility of monoclonal antibodies by increasing their potency, and provide Etches (2006) as support. Applicants argue

that the feature that oviduct cells do not fucosylate proteins was not disclosed in the prior art references, and that the invention is more than the predictable use of prior art elements. See pages 2-3 of the Response.

*Response to Arguments.* These arguments have been fully considered, but are not persuasive. Both Zhu (2005) and Etches (2006) are post-filing art, and therefore are not pertinent to the art at the time of filing, which is what is required under §103 (see statute which states that:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

Nothing in the as-filed disclosure discusses the advantage of using an avian oviduct cell with regard to a lack of fucosylation. Therefore, there is no support in the disclosure for this feature. Additionally, the increase in potency of monoclonal antibodies was not known at the time of the claimed invention. Given that one of skill in the art would have no knowledge of whether or not fucosylation would produce more potent antibodies, and additionally, there is no evidence in any of the cited art that using an oviduct cell, such as a tubular gland cell would *not* produce antibodies, it would have been wholly obvious for one of skill in the art to combine the art of Ditullio, Sanders, Mohammed and Michael to arrive at the claimed invention. There is nothing in the claims that requires an antibody with increased potency.

Raju is considered art at the time of filing. However Raju do not discuss that lack of fucosylation would provide a more potent monoclonal antibody, and further, do not discuss the fact that an avian oviduct cell, such as a tubular gland cell, could

not produce a monoclonal antibody. Raju provide no guidance to show that there would be any unpredictability in producing monoclonal antibodies in avian oviduct cells. Additionally, Raju are not looking at the ability for avian oviduct cells to product monoclonal antibodies. Raju discuss isolation of IgGs from chicken, but do not discuss that these IgGs were produced using oviduct cells. Therefore, Raju is not relevant to the instant invention because they generally discuss fucosylation of IgGs from chickens, but do not discuss the production of IgGs from specific chicken cells. The claims merely require the production of a heterologous antibody by an avian cell. There is no requirement for the lack or presence of fucosylation, or any potency required in the resultant antibody.

Additionally, the Examiner notes that obviousness can also be established in the prior art, even if the reasons to modify references are different:

MPEP § 2144 states:

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. >See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); < *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), *cert. denied*, 500 U.S. 904 (1991) (discussed below). Although *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

In the instant case, Ditullio teaches *in vitro* methods of producing heterologous antibodies. Sanders teach that tubular gland cells are capable of producing heterologous proteins, and Mohammed and Michael provide sufficient teachings for standard methods of isolation of immunoglobulins from cultured cells. Thus, it would have been obvious to one of ordinary skill in the art to apply the *in vitro* methods of Ditullio, with cells, such as those taught by Sanders, to produce and purify antibodies, as taught by Mohammed and Michael to attempt to optimize the isolation of antibodies directly from cultured cells, such as oviduct cells, which would be more efficient than producing a transgenic bird, and further, the cytomegaloviral promoter is a well-known and well-characterized promoter that would allow for optimal levels and patterns of gene expression, that utilizing an IRES element would facilitate expression of multiple genes, and that viral transduction is an efficient way to deliver a construct to a cell. All of the methods taught by the combined art are well known, well-characterized and predictable.

Accordingly, this rejection is maintained.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken Sanders, in further view of Mohammed, and in further view of Michael *et al.* as applied to claims 1-5, 9-17, 19-29, 62 and 63 above, and further in view of Larocca *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Claims 64-70 and 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken Sanders, in further view of

Mohammed, and in further view of Michael *et al.* as applied to claims 1-5, 9-17, 19-29, 62 and 63 above, and further in view of Ling *et al.* and Najarfian *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/  
Primary Examiner, Art Unit 1632